

Drug Enforcement Administration

[Docket No. DEA 950]

Importer of Controlled Substances Application: Meridian Medical Technologies

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Meridian Medical Technologies has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Such persons may also file a written request for a hearing on the application on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: The DEA requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to https://www.regulations.gov and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on https://www.regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register

Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on December 6, 2021, Meridian Medical Technologies, 2555 Hermelin Drive, Saint Louis, Missouri 63144, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

| Controlled Substance | Drug Code | Schedule |
|----------------------|-----------|----------|
| Morphine | 9300 | II |

The company manufactures a product containing morphine in the United States. The company exports this product to customers around the world. The company has been asked to ensure that its product, which is sold to European customers, meets the standards established by the European Pharmacopeia, administered by the Directorate for the quality of Medicines (EDQM). In order to ensure that its product will meet European specifications, the company seeks to import morphine supplied by EDQM for use as reference standards. No other activity for these drug codes is authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Matthew Strait,

Deputy Assistant Administrator.

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